VA/DoD Dyslipidemia Guideline/VA Lipid Performance Measures

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DISCLOSURE

- AFCAPS/TexCAPS PI 1989 to 1997
- Funding MSD

  —All Resources to Conduct Study Gift Proffered to USAF According to AFIs
- Cholesterol Treatment Trialist (CTTC) collaborating trialist

OBJECTIVES

- Understand the development process for a VA/DoD Guideline
- List key aspects of the Guideline
- Recognize that the VA/DoD Dyslipidemia Guideline is not a substitute for sound clinical judgment
- Articulate the basis for performance measures associated with the Dyslipidemia Guideline

Who Developed the CPG?

- Facilitator
- ECRI...Lit Searches/Evidence Grading
- Practicing clinical providers from DoD/VA
  - —Primary Care (NP, PA, Physicians)
  - —Subspecialists (Cards, Endo, Physiologists)
  - —Ancillary (Nutritional, Pharmacists, Epi)

Included stake holders from disciplines where dyslidemia was likely to be treated

What was Developed?

- Joint VA/DoD Dyslipidemia Gudieline
- 3 Algorithms: Screening, Initiate Tx, F/U Tx
- Annotations to support/explain algorithms
- Evidence Tables
- Appendices...drug, exercise, nutritional info
- Acrobat 7 PDF; operates like on the web
- 150 pages total; print your own hard copy

Where/How was the CPG Developed?

- Face to Face meetings
- Teleconferences
- Website
- Group Consensus
  - –Algorithms
  - –Annotations
  - –Evidence Grading {USPSTF}
- Guideline Champions...final decision authority

When was CPG Developed?

- Dec 2004 initial meeting
- Aug 2005 draft to OQP
- OQP approves May 06
- Final approval by Dr Perlin 9 Jun 06
- Posted OQP website 12 Oct 06

Why was the CPG Developed?

- CPG specifically applicable to VA system
- Adhere to best available evidence, not overstate
- Provide basis for performance measures which are ‘the ground zero’ of accountability
- To provide best care for Veterans while getting the most value for the VA healthcare dollar spent

Key Features: Like ATP III

- PRIMARY GOAL IS LDL BASED
- CHD RISK EQUIVALENCY
- Global 10 YEAR CVD RISK CALCULATION

  > 20%

  10-20 %

  < 10%

  'Global Management' of Multiple CV Risks

Key Features: Like ATP III

- HDL & TG Goals are Secondary
- Metabolic Syndrome
- 'Dyslipidemia' vs 'Hyperlipidemia'
- 'Very High Risk' Patients

  –ACS (AMI or True USA)

  –CVD w/ multiple poorly controlled RF (smoking, HTN, DM)

  –CVD w/ multiple RF for Metabolic Syndrome

  'Optional Therapeutic Goal'...LDL <70

Key Features: Unlike ATP III

- LDL Goal <100 for CV patients and/or DM
- LDL < 70 is not a 'hard target'
- Acknowledges moderate dose statin therapy (CTTC approach) is a reasonable therapeutic option for patients with CVD.
- Simpler (3 algorithms, 150 pages) vs NCEP

VA/DoD Dyslipidemia CPG Performance Measures

- LDL <100 for patient with CAD or DM
- ACS post discharge statin/lipid Tx
- LDL < 70 not a performance measure
- No HDL, TG or Non-HDL performance measures
- Bottomline...same measures as current FY 07 tech manual

CONCLUSIONS

- VA/DoD Dyslipidemia CPG developed at grass roots level
- Evidence-based with evidence rated recommendations
- Like NCEP in many aspects but differs
- The CPG is no substitute for clinical judgment
- Little anticipated change in performance measures

Date: November 9, 2006

Subj: Recommendations on LDL-C Lowering Goals

From: VHA Pharmacy Benefits Management Strategic Healthcare Group
VHA Medical Advisory Panel
Office of Quality and Performance
Chief Consultant for Cardiology
Chief Consultant for Diabetes

To: All VA Providers

1. The Department of Veterans Affairs and Department of Defense (VA/DoD) Clinical Practice Guideline for the Management of Dyslipidemia has been updated and approved by the Office of Quality and Performance. It is available at http://www.oqp.med.va.gov/cpg/DL/LIP_CPG/GOL.htm.

2. There has been an increasing perception that the LDL-C goal in patients with diabetes or cardiovascular disease should be <70 mg/dL, and that this is an evidence-based goal. This aggressive LDL-C target is in fact **NOT evidence-based** and the following recommendations are provided to reflect the updated VA/DoD Dyslipidemia Clinical Practice Guideline.

   - There is general consensus that unless contraindicated, patients who are admitted with an acute myocardial infarction (AMI) should be discharged and maintained on a moderate dose statin. Subsequent monitoring should target an LDL-C that is at least <100 mg/dL.

   - The benefit of lowering LDL-C to <70 mg/dL, independent of statin dosage, has not been demonstrated and to date no professional or governmental organization has endorsed a <70 mg/dL target value. The widely cited article in Circulation (2004) was an opinion paper by individual members of the National Cholesterol Education Program (NCEP), but not an official position paper. We note that the National Heart, Lung, Blood Institute (NHLBI) has maintained a 100 mg/dL LDL-C target value in the ACCORD trial. As most of you are aware, this would not be possible under the principles of beneficence if a lower target value was known to be efficacious. In support of

that position is a recent article by Hayward, et al., published in the Annals of Internal Medicine (October 2006, reference 5).

- The following represents the current guidance regarding goals for lowering LDL-C in VHA patients:

    - As recommended by NCEP ATP III and AHA/ACC continue with the goal of <100 mg/dL for high risk patients and await more conclusive data with regard to more aggressive LDL-C lowering.
    - After careful consideration, a clinician may consider a lower LDL-C goal as a therapeutic option in VERY HIGH RISK patients. **Very High Risk** patients are those with recent documented ACS (AMI or true unstable angina), or those with established cardiovascular disease plus multiple major risk factors (smoking, hypertension, diabetes) that are poorly controlled and/or multiple risk factors of the metabolic syndrome (high triglycerides >200 mg/dL plus non-HDL-C >130 mg/dL with low HDL-C <40 mg/dL).
    - Clinicians are reminded to consider the harms of high dose statin therapy and to educate all patients on statins to recognize and report symptoms of myopathy. A review of a patient's history for factors that may predispose them to adverse events from statins (e.g. renal or liver impairment, hypothyroidism, alcohol abuse, frailty, drug-drug interactions, etc.) is essential in attempting to minimize toxicity. Although the risk for serious muscle toxicity increases as the dose of statins is increased, the risk remains low (<1%).
    - Because of the high rate of study dropouts (30-34%), as seen in PROVE-IT and A to Z, and the well known poor long-term adherence rates with statins, reinforcement of the chronicity of statin therapy with the patient and checking for signs of statin nonadherence prior to altering lipid-lowering treatments is recommended.

3. Further background information and a summary review of the evidence can be found in the attached document.

Sincerely,

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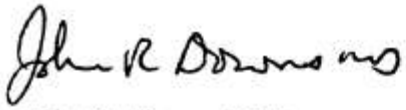

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STVHCS Dyslip Efforts

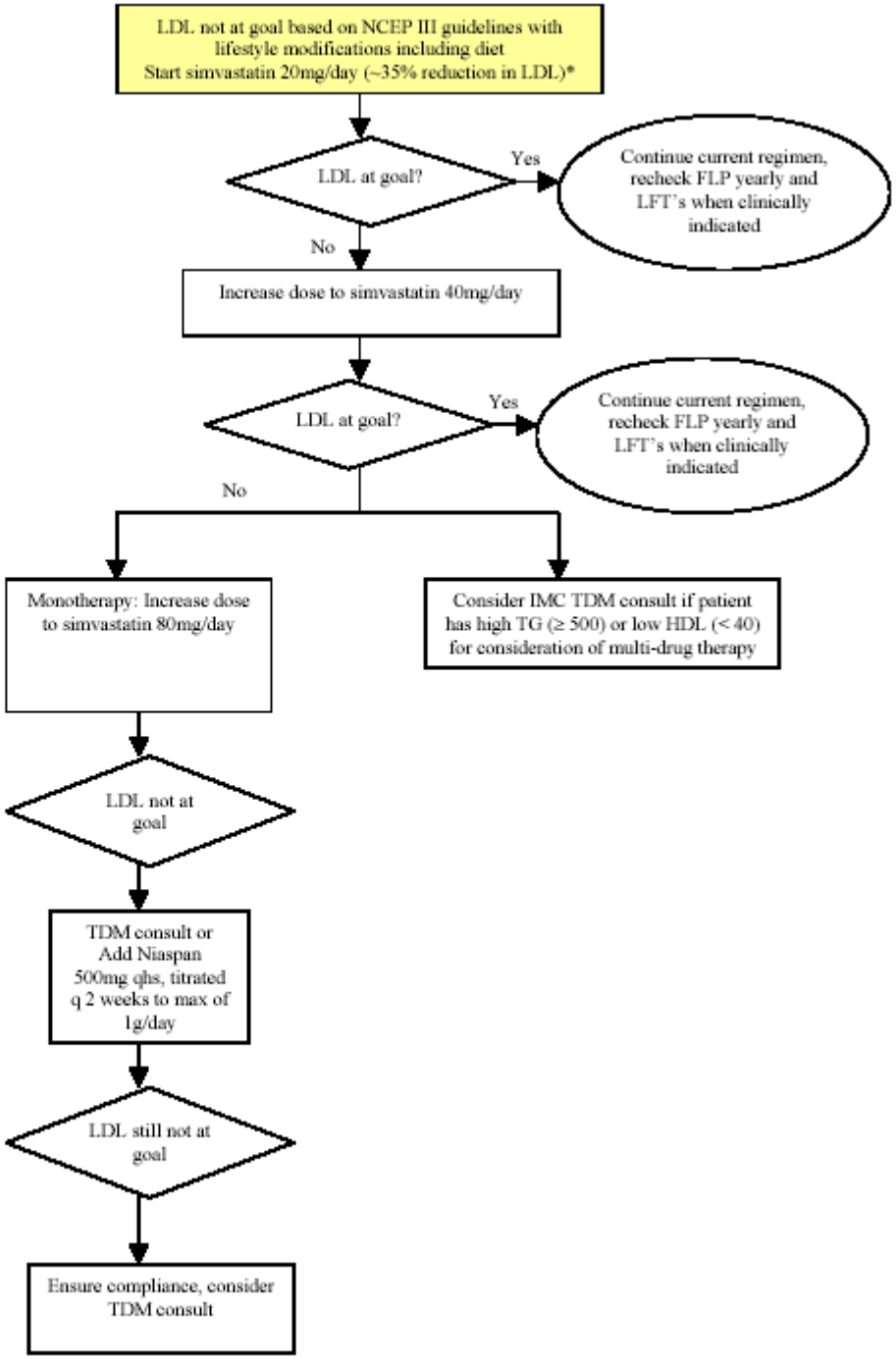
- STVHCS Dyslip Algorithm...KISS Principle
  - PharmD Clinical Trial Evidence Tables
- Electronic Non-Formulary review process
  - MAP Ezetimibe Criteria
  - Local Atorvastatin/Fenofibrate Criteria
- Physician Champion...OPC Presentations
- Simva Dosing and split tab strategy

Clinical Pearls

1. The LDL goal for patients with ischemic heart disease and diabetes is <100mg/dL; an OPTIONAL LDL goal of < 70 relates to patients at very high risk such as ACS♠
2. The incidence of rhabdomyolysis is very low with moderate dose (simva 40 or equivalent) statin therapy (0.023%)♥
3. Patients should receive additional liver function tests prior to titration & 3 months after titration to the 80-mg dose of a statin, and periodically thereafter (e.g., semiannually) for the first year of treatment.
4. Atorvastatin, ezetimibe, fenofibrate, and marine fish oil are non-formulary agents
5. Niaspan is an extended-release formulation of niacin that is associated with less flushing and itching than other forms of niacin, should take non-enteric coated ASA 325 mg 30 minutes prior to dose
6. The combination of statin and fibrate therapy increases the risk of rhabdomyolysis up to 5% (NNH 20)

♠ VA/DoD Lipid Guidelines 11-06

♥ Lancet 2005;366:1267-1278 Cholesterol Treatment Trialist Collaboration



Lipid Police

Lipid Lecture

STVHCS FY 06 Utilization Data

Drug	Oct 05	Sept 06
Atorva	$83,803 (895)	$65,859 (569)
Simva	$225,999(6811)	$186,965 (6791)
Fluva	$1,027 (44)	$2,578 (105)
Lova	$5,581 (217)	$8,806 (321)
Prava	$8,728 (79)	$1,432 (12)
Rosuva	$500 (7)	$164 (5)
Ezetimibe	$60,202 (703)	$18,447 (195)
Niaspan	$21,276 (797)	$27,021 (916)
Fenofibrate	$11,606 (4-06) (141)	$4,803 (66)
Gemfibrozil	$8,943 (820)	$9,442 (817)
Total$	$427,665	$325,517

Example Cases

Case 1

- 79 year old male with HTN (BP 140/48), DM (Hb A1c 6.2), CAD; on simvastatin 40 mg daily + ezetimibe 10 mg daily. Current lipid profile- TC 137 LDL 62 HDL 43 TG 160. Endocrinologist wants to continue regimen. Now on simva 60 with LDL 64.
- Recommendations-
  - Approve
  - Disapprove
  - Alternative therapy

Case 2

- 65 year old male with HTN (BP 157/64), CAD (ACS 2-04 with PCI & stenting). In 8-04 while on simvastatin 40 mg daily his labs were LDL 62 HDL 64 TG 61 AST 71 ALT 76. Simvastatin was stopped by cardiology and patient started on colestipol + ezetimibe. Current lipid profile- LDL 79 HDL 55 TG 70 AST 68 ALT 77. PCP wants to continue regimen based on cardiology's recommendation.
- Recommendations-
  - Approve
  - Disapprove
  - Alternative therapy

Case 3

- 58 year old male with DM (Hb A1c 7.9) on atorvastatin 20 mg daily provided by LMD. Patient's LDL 33. Wants to receive atorvastatin from VA. No history of simvastatin use in VA pharmacy files.
- Recommendations-
  - Approve
  - Disapprove
  - Alternative therapy

Case 4

- 62 year old male with DM (Hb A1c 8.1), CAD on simvastatin 40 mg daily + gemfibrozil 600 mg twice daily with LDL 43 HDL 25 TG 1067. An academic cardiologist wants to add ezetimibe. Follow-up lipid profile on simva + gem 8 months later LDL 55 HDL 29 TG 407.
- Recommendations-
  - Approve
  - Disapprove
  - Alternative therapy

Case 5

- 50 year old male with DM (Hb A1c 11.5). On simvastatin 40 mg daily his LDL 19 HDL 34 TG 1116. PCP wants to start ezetimibe.
- Recommendations-
  - Approve
  - Disapprove
  - Alternative therapy

Case 6

- 53 year old male with CAD. On simvastatin 40 mg daily his LDL 61, LDL 49, & LDL 57. Patient was seen by cardiology fellow with an LDL 107. Refill records indicated missed doses. Fellow wanted to switch to atorvastatin. When request was denied, he told the patient that pharmacy was denying him medications that would save his life. Follow-up LDL on simva 40 is 44.
- Recommendations-
  - Approve
  - Disapprove
  - Alternative therapy

QUESTIONS?

Case 7

- 58 year old male with DM (Hb A1c 6.8) on atorvastatin 40 + gemfibrozil with LDL (49 to 92) & TG (112 to 423). When TGs were 241, an academic endocrinologist switched patient to fenofibrate with follow-up TG (113 to 426). Wants to continue therapy.
- Recommendations-
  - Approve
  - Disapprove
  - Alternative therapy

Case 8

- 59 year old male with HTN (BP 123/74), CAD on simvastatin 80 mg daily + ezetimibe 10 mg + WelChol 1875 twice daily with LDL 29 HDL 43 TG 293. Wants to continue therapy. Now on simva 80 with no follow-up labs yet.
- Recommendations-
  - Approve
  - Disapprove
  - Alternative therapy

Case 9

- 73 year old male with HTN (BP 118/60), DM (Hb A1c 8.6), CAD. Patient only comes to VA to get meds. He is on atorvastatin 80 mg daily + ezetimibe 10 mg daily with TC 82 in 3-05 and TC 116 in 2-06. PCP wants to provide current therapy.
- Recommendations-
  - Approve
  - Disapprove
  - Alternative therapy

Case 10

- 73 year old male with CAD (CABG 2004). Patient is on pravastatin 80 mg daily with LDL 97 HDL 31 TG 77 AST 97 ALT 54. PCP wants to add ezetimibe to achieve LDL goal of < 70. Still on prava 80 with LDL 93.
- Recommendations-
  - Approve
  - Disapprove
  - Alternative therapy

Case 11

- 61 year old male with DM (Hb A1c 8.8), CAD (+ Th 2002). Patient presented to PCP with LDL 143 HDL 40 TG 65. Patient was started on ezetimibe monotherapy. Now has LDL 135 HDL 39 TG 110. PCP wants to renew ezetimibe. Now on simva 20 follow-up labs pending.
- Recommendations-
  - Approve
  - Disapprove
  - Alternative therapy